Docket: 2004D-0369 - Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by Bioengineered Plants Intended for Food Use

We are writing to urge you to withdraw the proposals contained in FDA's "Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use".

The stated purpose of this Guidance is to set up a voluntary mechanism for "early food safety evaluation" of new proteins from experimental bioengineered or genetically engineered plants intended for food use, which are being field tested. This is purportedly to address the likelihood that cross-pollination and commingling of seeds will occur, resulting in the presence of untested novel proteins in the food supply.

However, the proposed "early food safety evaluation" is inadequate for genuine food safety evaluation, with companies and developers only encouraged to voluntarily provide a synopsis of safety data and information about the new protein, focussed mainly on toxicity and allergenicity. The scope of the proposed data and information that should be provided is limited, and there is no mention of the need for comprehensive animal feeding trials or tests for unintended effects caused by genetic engineering. Such unintended effects are an acknowledged risk factor by the Codex Alimentarius Commission, the joint agency of the World Health Organization and the UN Food and Agriculture Organization, responsible for the international regulation of food safety.

Furthermore, the Guidance fails to specify exactly how the tests are to be conducted. It is likely that, without specific and mandatory test protocols, companies will fail to sufficiently provide the necessary scientific information to prove safety beyond reasonable doubt.

If the FDA is serious about conducting a food safety evaluation for genetically engineered foods, it should withdraw the recommendations proposed in this Guidance. Instead, the FDA should devise strict rules and procedures to prevent contamination of the food supply with transgenic proteins and should replace its current non-rigorous voluntary biotechnology consultation process with a mandatory, science-based and rigorous review process designed to ensure food safety. Such safety assessments should be long term, intergenerational and on the whole food, not just on the new substance that the genetically engineered plant is designed to produce.

The FDA guidance as it stands would simply permit companies and developers to allow experimental genetically engineered crops to enter the U.S. food supply. If the new proteins are deemed by the FDA to not raise food safety concerns, this effectively permits contamination of both genetically and even non-genetically engineered crops with experimental and inadequately tested transgenic proteins. As citizens of developing countries that are likely to import food from the U.S., our food supplies will also be affected. This is unacceptable, as our choice is to remain GE-free, given the health, environmental and socio-economic hazards posed by genetically engineered organisms.

It is unclear how the FDA, with this Guidance, intends to comply with other countries' domestic regulations for unapproved or unauthorized genetically engineered organisms. Most developing countries lack the regulations, capacity and means to enforce biosafety

legislation or bans, and the reality remains that unapproved genetically engineered organisms may slip through. Short of FDA specifically notifying importing countries of the presence of unapproved novel proteins in U.S. food exports and providing the necessary reference materials to facilitate detection and identification, the only way other countries can determine if there is presence of unapproved genetically engineered material is to randomly test for their presence. However, this shifts the burden and costs of testing on the recipient countries and does not provide a guarantee of detection and identification.

We are especially concerned at FDA's reported intention to use this Guidance as an international model to address the presence of low levels of genetically engineered plant material in non-genetically engineered crop fields. This is nothing short of forcing other countries to accept contamination by genetically engineered plants and food, when many have expressed serious concerns over their potential adverse impacts. Already 111 countries have ratified the Cartagena Protocol on Biosafety - the only international law to specifically regulate genetic engineering - which is underpinned by the Precautionary Principle. The Protocol also specifically preserves the right of importing countries to reject or place conditions on the import of genetically engineered organisms intended for food or feed, and to formulate their own biosafety legislation, which can be crafted to keep them GE-free.

Given the seriousness and far-reaching impacts of the FDA's proposals, we will continue to raise this issue with our Governments, and we pledge to work towards ensuring zero tolerance for unapproved and experimental transgenic proteins in the food supply, and for our countries to remain GE-free.

Yours sincerely,

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